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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,675	07/09/2001	Olga Bandman	PF-0531 USN	8931

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,675

Applicant(s)

BANDMAN ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-62 is/are pending in the application.
- 4a) Of the above claim(s) 52,53,55-57 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-51,54,58,59,61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/18/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-43 have been canceled previously. Claims 52-53, 55-57, 60 have previously been withdrawn from consideration. Claims 45-59, 54, 58-59, amended claims 44, 50-51 (6/18/04) and new claims 61-62 are under consideration.
2. Receipt of applicant's arguments and amendments filed on 6/18/04~~2~~ is acknowledged.
3. Applicant's arguments filed on 6/18/04 have been fully considered but were non-persuasive. The issues remaining are stated below.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101/112, first paragraph

5. Claims 44-51, 54, 58-59, 61-62 are rejected under 35 U.S.C. § 101.

This rejection is maintained for reasons of record set forth at pages 3-7 of the previous Office action (3/18/04).

Applicants argue that the protein of amino acid sequence set forth in SEQ ID NO:3 of the instant invention is identical to the proteins named p34SEI1 and TRIP-Br1 and that a post-filing article regarding p34SEI1 protein indicates that p34SEI1 protein antagonizes the function of p16INK4a which inhibits the cyclin-dependent kinases CDK4 and CDK6. Applicants have cited Sugimoto et al. (1999) in this regard for the function of p34SEI1 protein. Furthermore, Applicants have also cited Hsu et al. (2001), another post-filing sate article, that reports that TRIP-Br1 (which is identical to p34SEI1 protein of Sugimoto et al.) is a transcriptional regulator that stimulates E2F-1/DP-1 transcriptional activity. Therefore, Applicants argue that the protein of the instant invention has function with biological significance. However,

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contrary to Applicants arguments, on page 27 of the instant specification, Applicants disclose that “expression of CECRP is closely associated with cell proliferation”. However, bleach or gasoline are reagents that can affect cell proliferation. In the instant specification, there is no specific function for the claimed protein recited. The teaching about the specific function of the claimed CECRP protein that is recited in the post-filing date articles, is not recited in the instant specification. There is no demonstration of the biological function of the instant protein but an assertion that the protein has homology to cell cycle regulation proteins (page 3, lines 2-28).

There is a whole list of disparate diseases recited on page 40 of the instant specification, the diseases ranging from cirrhosis, heart disease and infections. However, Applicants have failed to recite a specific and substantial utility for this particular protein because Applicants have failed to disclose a nexus between the expression of the claimed protein and any of these conditions. Therefore, Applicants are claiming diagnosis of unrelated diseases using the polynucleotide encoding the instant protein, which if assertions are credible, it would appear that a the instant protein is the “magic bullet” which medical researchers have been seeking since medical research began. This would be akin to medical research’s version of the perpetual motion machine. However, given the disclosure of no data of any kind, nor the establishment of any connection or correlation of the asserted protein with any particular disease or disorder, the assertions cannot be considered credible. The assertion of utility in this application flies in the face of medical and scientific reality. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. Accordingly, the specification fails to provide either a specific and

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substantial asserted utility, or a well-established utility for the claimed protein, thus, no specific and substantial asserted utility, or a well-established utility can be established for the claimed protein in the diagnosis of the various recited diseases.

The following is an excerpt from M.P.E.P. 2138.05:

Utility for the invention must be known at the time of the reduction to practice. *Wiesner v. Weigert*, 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); *Azar v. Burns*, 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to practice unless the composition and the product produced by the method have a practical utility); *Ciric v. Flanigen*, 185 USPQ 103, 105 - 6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); *Engelhardt v. Judd*, 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); *Rey - Bellet v. Engelhardt*, 181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an

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indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.)."

Claims 44-51, 54, 58-59 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed protein, therefore, there is no specific and substantial asserted utility or well established for the claimed protein.

With respect to the new limitation "at least 95% identity" in claims 44, 51 and 61-62, Applicants argue that to expedite prosecution the limitation "at least 90% identical" has been substituted with "at least 95% identical" and this limitation avoids the written description and enablement rejections. However, contrary to Applicants' arguments, the instant specification would still fail to adequately describe and enable an isolated protein that is at least 95% identical to the polypeptide of SEQ ID NO:3 for the reasons set forth on pages 7-8 of the last office action of 3/18/2004. Since Applicants have failed to show the error in this rejection by the Examiner or have failed to delete the "% identity" limitation from the claims, the rejection of this limitation is being maintained for the reasons of record.

Claim rejections-35 USC § 112, second paragraph

6. Claims 44-51, 54 and 58-59, 61-62 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44 and 51 are rejected as vague and indefinite for reciting "cell cycle regulating activity".

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This rejection is maintained for reasons of record set forth at page 8 of the previous Office action (3/18/04).

Applicants argue that they have established an actual effect that the claimed protein has on the cell cycle from which one can determine the metes and bounds of the term “cell cycle regulating activity” since Applicants have demonstrated that the claimed protein is associated with unregulated growth of tumor cells, i.e. unregulated cellular proliferation. However, contrary to Applicants’ arguments, the specification of page 27, lines 17-18 fails to demonstrate what is recited in the post-filing date references of Sugimoto et al. Therefore, the instant specification fails to provide a definition of the term “cell cycle regulating activity”. Therefore, the metes and bounds of this term remain unclear.

Similarly, with respect to new claims 61-62, which recite the limitation, “regulates cell proliferation”, it is unclear whether the claimed polypeptide attenuates or exacerbates cell proliferation. Therefore, the metes and bounds of the term are unclear.

Claims 45-50, 54, 58-59 are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
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July 8, 2004